

Challenges in Gender Representation Across Clinical Trials-How Can We Impact This?

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COVIDIEN

COVIDIEN VASCULAR THERAPIES ORGANIZATION



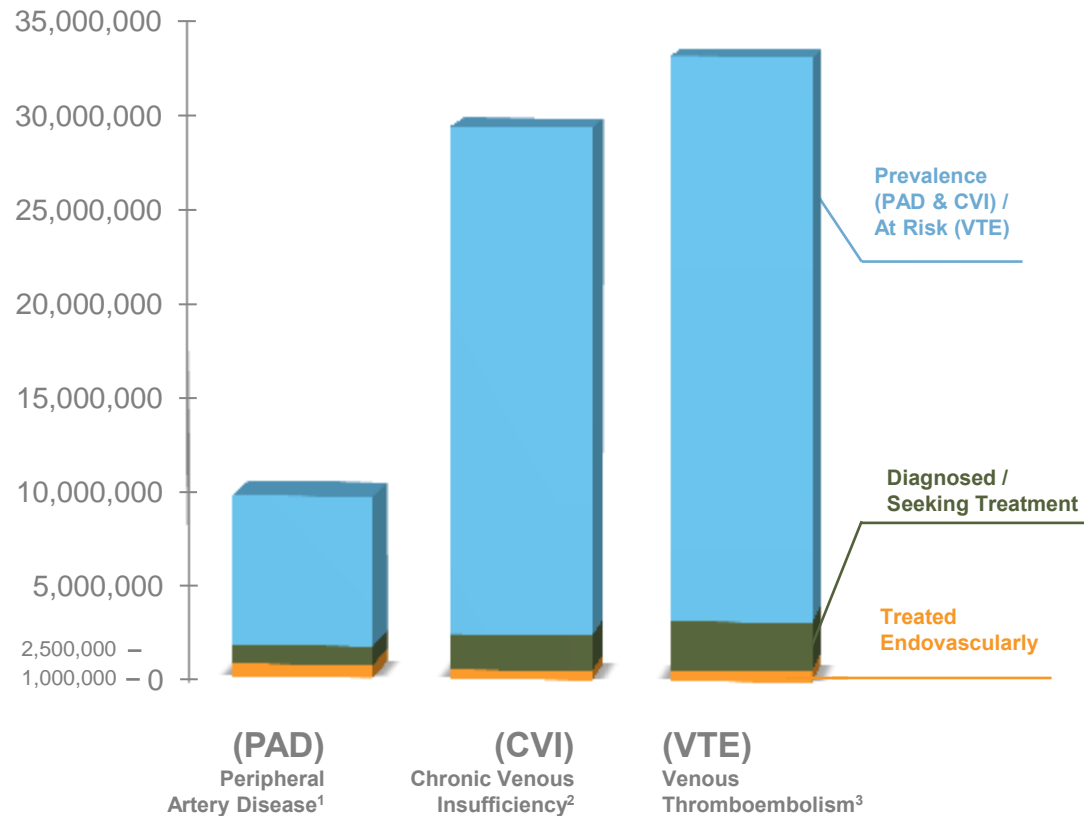
- **PERIPHERAL VASCULAR**

 - **Endoarterial**
Peripheral Artery Disease (PAD)
 - **Endovenous**
Chronic Venous Insufficiency (CVI)
Deep Vein Thrombosis Treatment (DVT)
 - **Venous Solutions**
DVT Prevention
Dialysis Access
- **NEUROVASCULAR**

- **INTERVENTIONAL
HYPERTENSION**

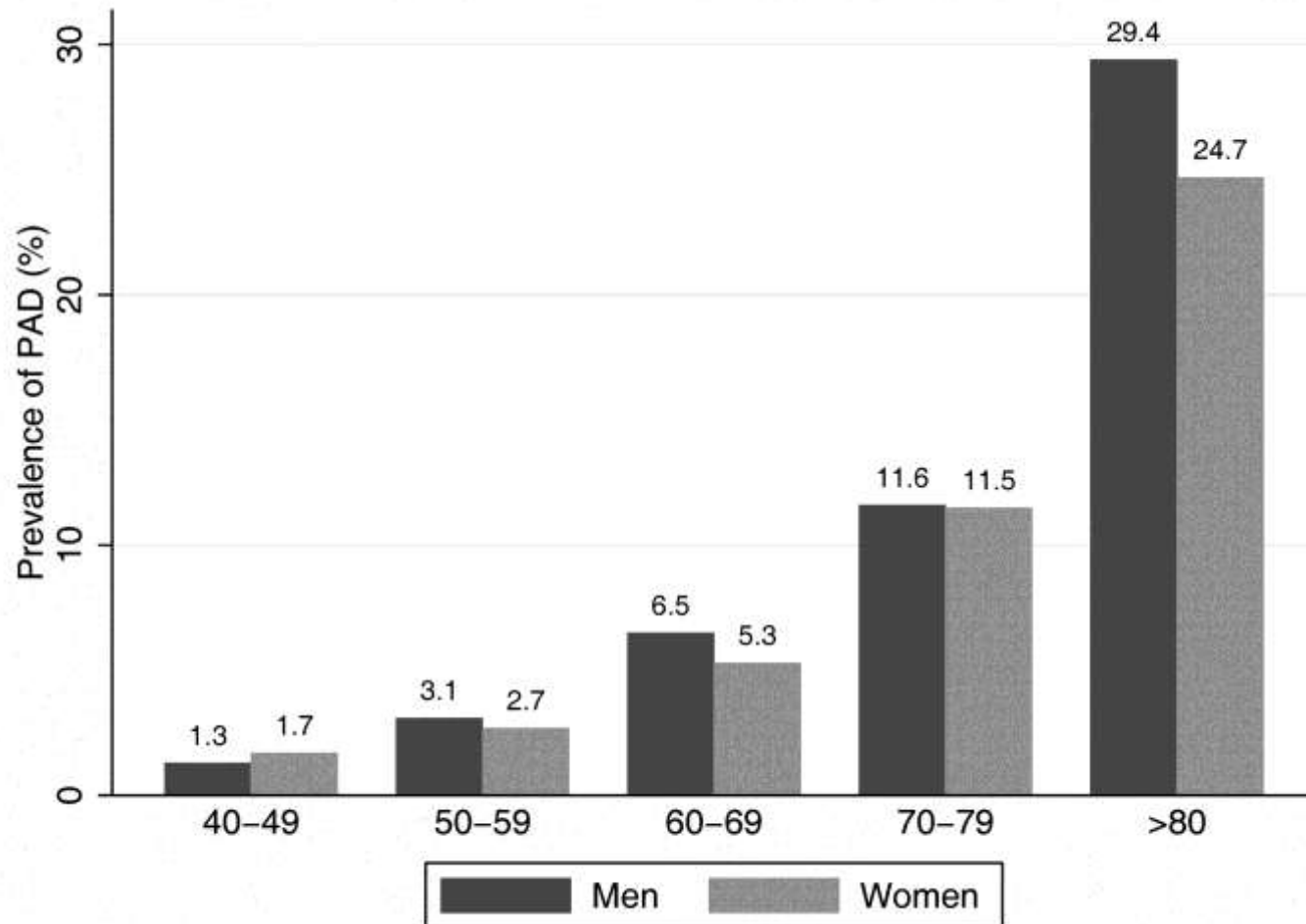
VASCULAR DISEASE BY THE NUMBERS

With millions of patients affected by vascular disease, only a small fraction of patients are currently receiving endovascular treatment.



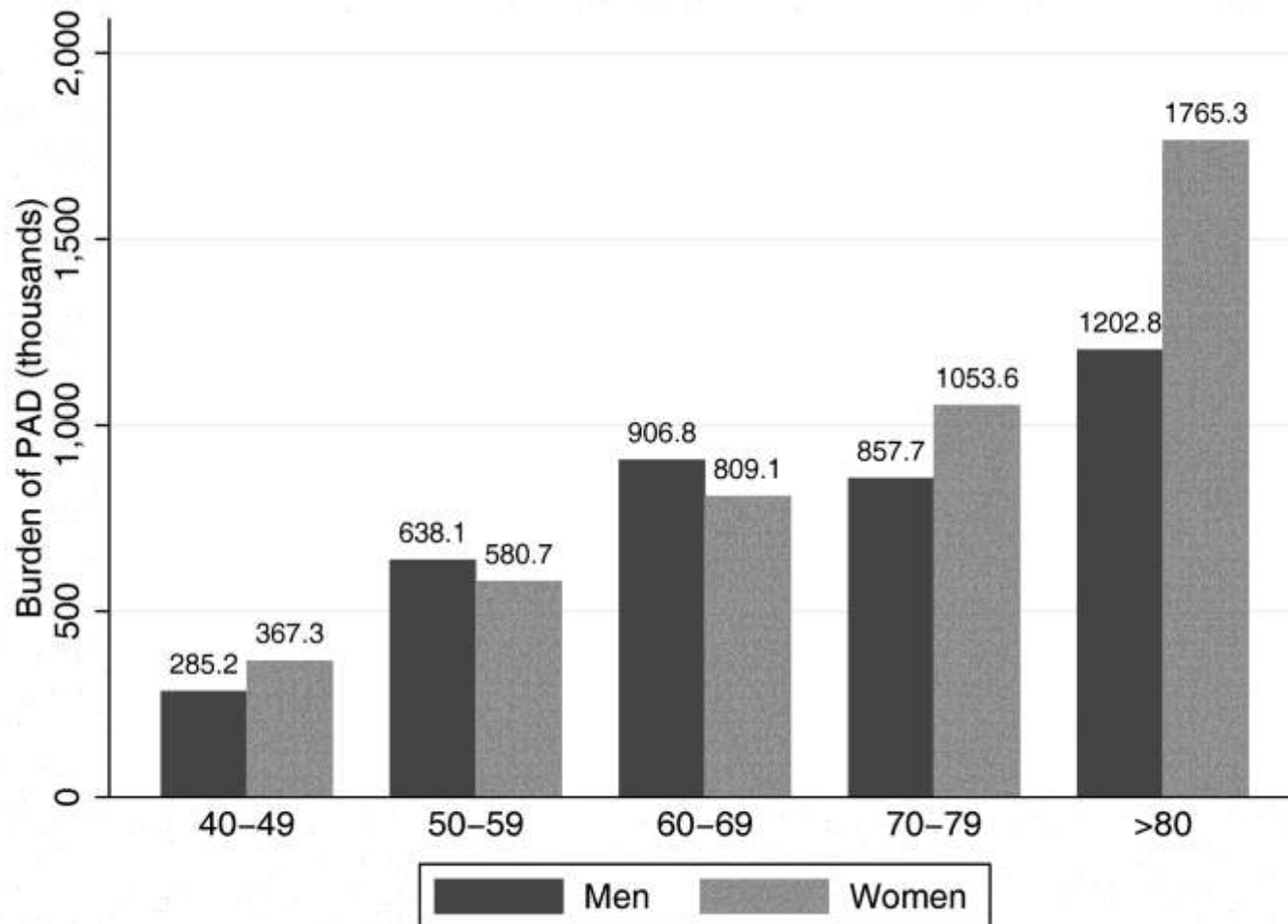
*US only data

Gender-specific prevalence of peripheral artery disease (PAD) by age group.



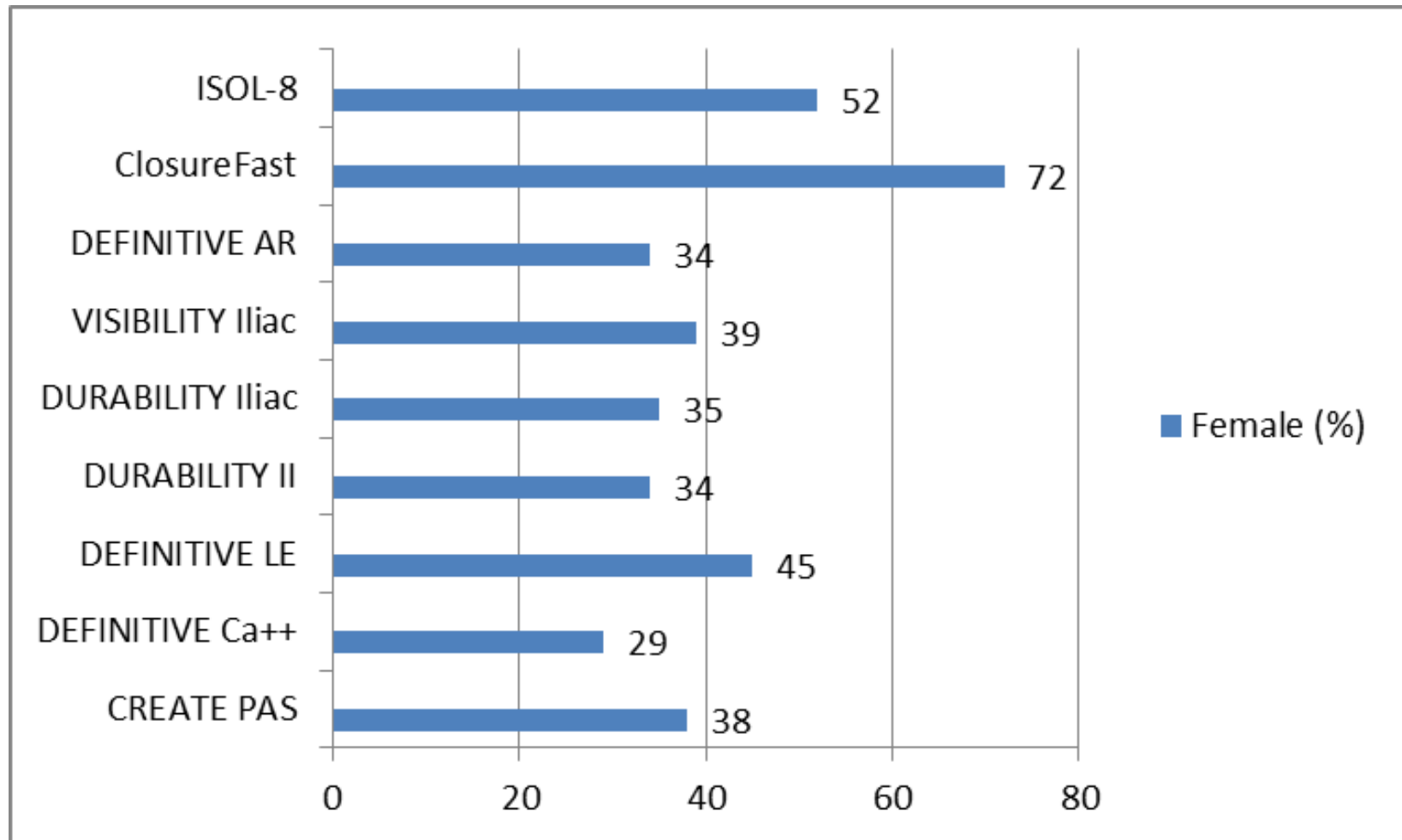
Hirsch A T et al. Circulation 2012;125:1449-1472

Estimated gender-specific burden of peripheral artery disease (PAD) by age group.



Hirsch A T et al. Circulation 2012;125:1449-1472

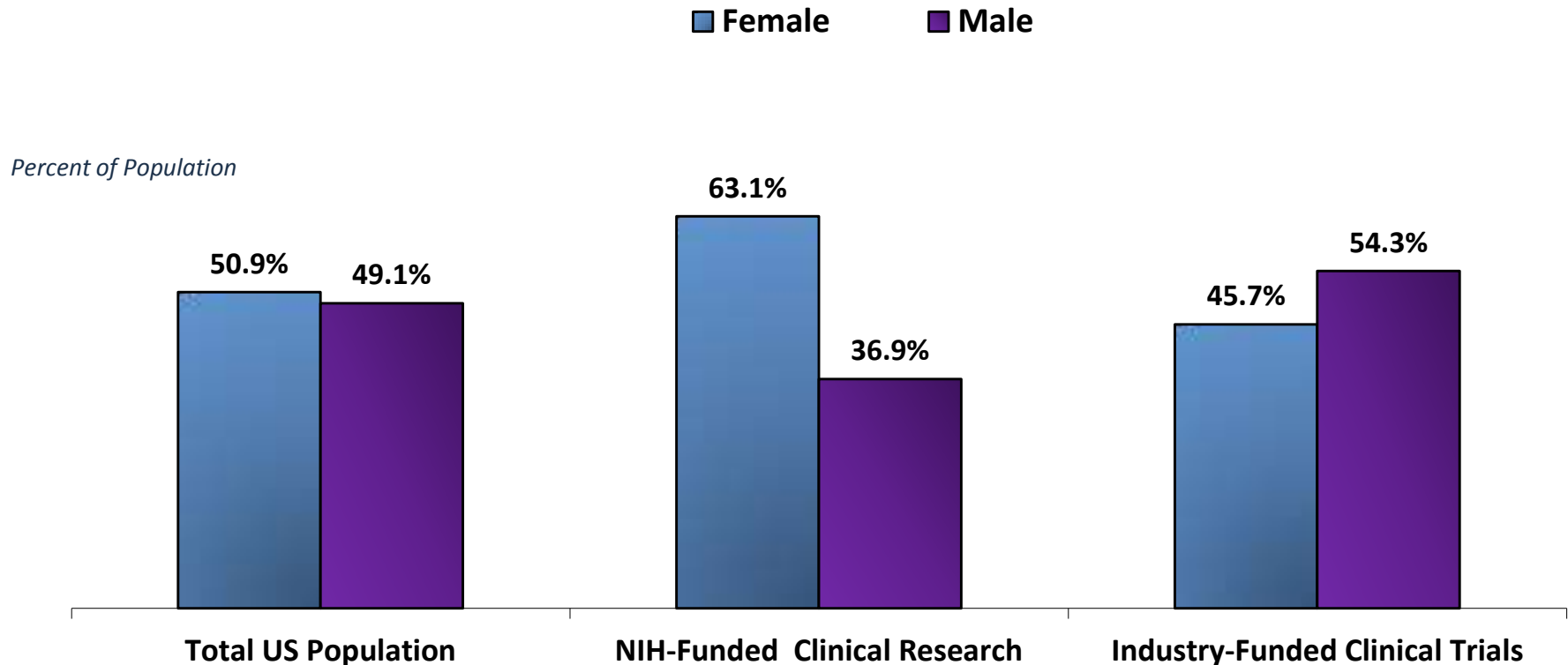
Varied Representation of Women Across Covidien's Peripheral Vascular Research



Varied Representation of Women Across Covidien's Research (outside of PV)

Division	Study	Device	Female
Hypertension	RAPID I	OneShot RDN catheter	42% (21/50)
NV	BRAVO	Onyx AVM embolic	38% (45/117)
NV	SWIFT	Solitaire FR and MERCI	52% (75/144)
NV	STAR	Solitaire FR	60% (123/205)
NV	PUFS	Pipeline Embolization Device	89% (96/108)
NV	SOLARE	Axiom aneurysm coils	84% (53/63)
Surgical	AbsorbaTack Inguinal Hernia	AbsorbaTack	8% (8/104)
Surgical	AbsorbaTack Ventral Hernia	AbsorbaTack	43% (47/110)
Surgical	GROTEHUIS	DuraSeal Xact	40.0% (8/20)
Surgical	FRANSEN	DuraSeal Xact	30.0% (6/20)
Surgical	Hemostatic patch – EU Liver study	Hemostatic Patch	40% (20/50)
Surgical	Veriset™ (Soft Tissue)	Hemostatic Patch	33% (10/30)
Surgical	Permacol IDE (infected mesh)	Permacol	37.5% (3/8)
Surgical	PROPHETI	Permacol	39% (23/59)
Surgical	PleuraSeal Sealant System	PleuraSeal Sealant System	50.0% (115/230)
Surgical	SILS	SILS	74% (148/200)
Surgical	DS3 IDE Study	Spinal Sealant System	60.2% (59/98)
Surgical	SprayShield™ Adhesion Barrier System	SprayShield	27.3% (3/11)
Surgical	Hemorrhoid Head to Head	stapler	44.3% (66/149)
Surgical	Hemorrhoid Small Study	stapler	33% (9/27)
Surgical	Tri Staple Pulmonary Resection	stapler	63.8% (30/47)
Surgical	V-Loc	V-Loc Absorbable Wound Closure Device	93.0% (213/229)
Surgical	Premy RCT	Prevadh kit	100% (61/61)
Surgical	Permacol Retrospective (US and Europe) STR	Permacol	52.8% (181/343)
Surgical	Birk - Progrid	Parietex Progrid	7.7% (13/169)
Surgical	Uretex™ TO Study (uro-gynecological study) for urinary incontinence	Uretex TO	100% (228/228)
Surgical	Ugytex™ Study (uro-gynecological study)	Ugytex	100% (238/238)
Surgical	Progrid RCT	Parietex Progrid	0% (0/603)
Surgical	Maserati100	Permacol Paste	10% (3/30)
Surgical	Permacol - EMEA observational Study -Enhance	Permacol	42.4 (39/92)

Gender Volunteer Disparities in Clinical Research



How Can We Impact This?

- Patient Awareness Campaigns?
- Investigator Selection

Scope of Support Programs Provided

Comprehensive, customizable tools enable proactive screening for PAD, accelerating patient identification and referral for earlier treatment.



- Community Awareness
- Hospital Programs & Marketing
- Referral Community Outreach
- Internal Screening



- Screening and patient education resources
- PAD screening event planning materials

Partnering in Market Development: Rethink Varicose Veins Campaign



This integrated educational campaign unites three leading medical societies under one common goal:

EDUCATING PROFESSIONALS TO
ADVANCE THE TREATMENT OF
VARICOSE VEINS AND CVI.

COALITION PARTNERS:



*Logos are trademarks of their respective owners



CVI Awareness

Campaign Spokesperson: Summer Sanders



“I suffered from heavy and achy legs for too long. Take control of your health. Visit www.RethinkVaricoseVeins.com to find a vein specialist and learn more about my story.”

— Summer Sanders
Olympic Gold Medalist and TV Host



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Rethink Varicose Veins: Campaign Resources



Quick Screen

Posters



Physician Locator



Brochures



Electronic Toolkit



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Promotional Posters, Flyers, and Slides

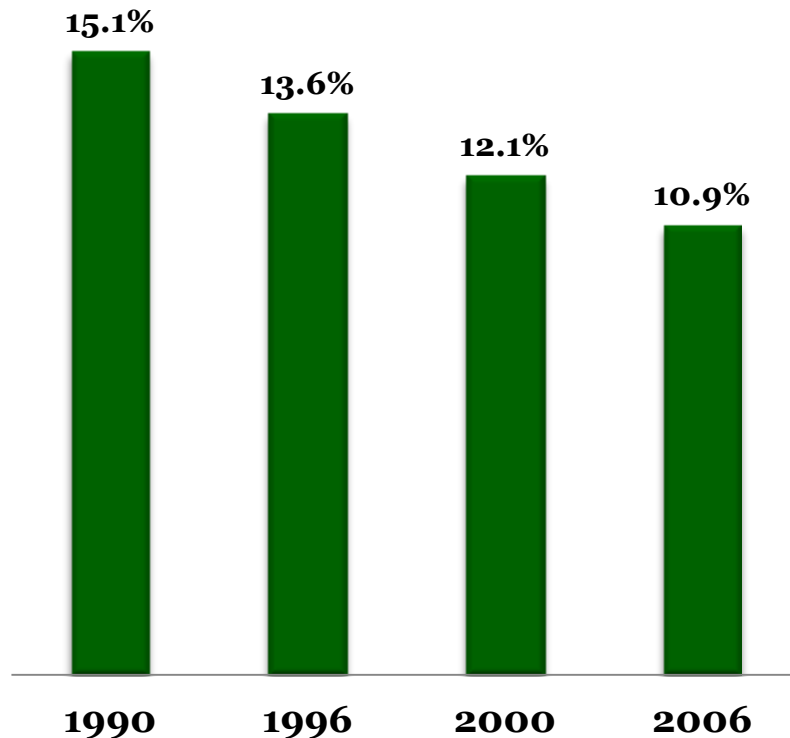
POSTERS

Help Get the Word Out! You can help raise public awareness of clinical trials by displaying these posters in your clinic or hospital. They were specifically designed for this NIH clinical research initiative and are the result of extensive testing through focus groups, in-depth interviews, and online surveys. We encourage you to use them in your clinics, waiting and exam rooms, labs, public spaces, and other areas. You may download these posters for free and print them on a standard office printer or use a commercial printer.



Decreasing Number of Female PIs

Proportion of US Principal Investigators Who are Women



- Disproportionately high willingness to participate in clinical research; far lower willingness to participate in industry funded clinical trials
- Declining proportion of female investigators
- In the literature: Wagner et al, 2007; Ley and Hamilton, 2008;

Investigator Disparities by Gender

	Female	Male
Percent of all board certified physicians conducting industry-funded clinical trials	10.9*	16.9%
Average Age	47*	54
Average total number of clinical trials conducted since beginning involvement	11	33
Average number of patients seen annually	1,996*	3,649
Research Center Settings: AMC/Practice	78%/22%*	66%/34%

•significant at p<.05 level

Final Thoughts

- Need to Understand Disease State as it Relates to Gender Differences.
- Need to Target Appropriate Patient Population for Clinical Trials.
 - Targeted Patient Awareness
 - Investigator Selection

